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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,735	02/19/2004	Gian-Carlo Covino	34064/US	3411
7590 David E. Bruhn, Esq. DORSEY & WHITNEY LLP Intellectual Property Department 50 South Sixth Street, Suite 1500 Minneapolis, MN 55402-1498			EXAMINER MENDEZ, MANUEL A	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 03/02/2011	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/782,735

Applicant(s)

COVINO ET AL.

Examiner

Manuel A. Mendez

Art Unit

3763

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-19 and 22-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-19, and 22-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 recites the limitation "the center point of the bending beams" in line 8.

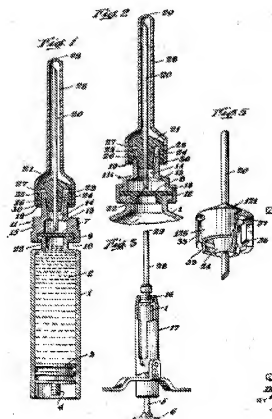
There is insufficient antecedent basis for this limitation in the claim. It is noted that the "bending beams" are not defined structurally in the claim. Therefore, any reference to an element of the "bending beams" must be considered as lacking antecedent basis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

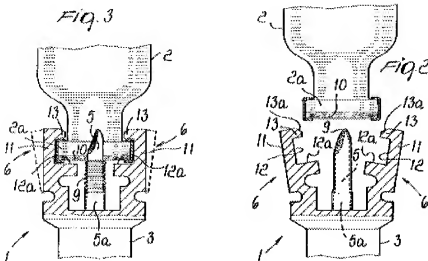
Claims 1-5, 7-11, 12, 13-15, 16, 17-19, and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Ashkenaz** et al. (US 2,823,743; hereafter Ashkenaz) in view of **Azzolini** (US 6,575,955), **Uchida** (US 5,445,631), **Aoki** et al. (US 4,936,841; hereafter "Aoki") or **Lynn** et al. (US 5,137,524; hereafter Lynn).



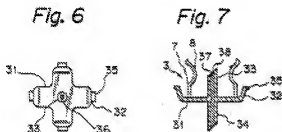
The **Ashkenaz** patent discloses a fixing device for injection needles for pushing onto a thread of an injection apparatus, wherein said fixing device is formed as a cap comprising an open end and a closed end which holds a needle perpendicularly in the middle of the fixing device, and a surface area of the fixing device is slightly spring-elastic in its circumference and comprises at least three cams directed to said thread, said cams perpendicularly engaging with flights of the thread when said cap is pushed onto the thread, wherein each cam comprises at least one notch arranged parallel to the surface circumference.

The Ashkenaz patent does not disclose a cap having at least five spring elements. However, designing an injection apparatus having multiple spring elements

would have been considered conventional in the art as evidenced by the teachings of Azzolini (US 6,575,955) or Uchida (US 5,445,631).

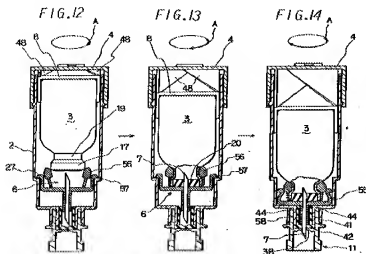


In figures 2 and 3 above, the Azzolini patent shows an infusion system having two spring elements.



Furthermore, the Uchida patent, in figures 6 and 7 above, shows a design having four spring elements. Accordingly, based on the evidence provided above, factually it can be concluded that spring elements are well known in the art and can be duplicated in various infusion system designs. Therefore, whether the infusion system is designed

to have two or more spring elements, such design would have been considered an obvious choice in the process of designing the infusion system.



Finally, the examiner has included the Aoki patent in this rejection to further demonstrate the conventionality of spring elements. As can be observed in figures 12, 13, and 14, Aoki shows a spring element having a notched cam (56) and a bending beam that supports the notched cam (56). As far as patentability, whether the notched cam and the bending beam are disclosed as separate elements or as an integral piece, the case law on point suggests that such differences would have been considered an obvious design choice.

In relation to **claims 2 and 18**, Ashkenaz shows in figure 5 a cap wherein each cam has two tips, one tip below number 26 and the other tip below number 27. In relation to **claims 3, 16, 17, and 19**, figure 5 shows cams having three points of contact wherein the points of contact can be in different planes. Notably, when a needle is introduced into the vial, the cams that are mounted in skirts (125) will move laterally into different planes. In relation to **claim 4**, figure 5 shows the distance between the tips is

approximately equal to the height of the flight. In relation to **claim 5**, figure 5 shows three skirts (125) acting as springs. In relation to **claim 12**, figures 1, 2, and 5 show an injection apparatus comprising a storage container wherein a needle penetrates into the storage container when the cap is pushed onto the thread of the injection apparatus.

In relation to **claims 14-15**, since caps and needles would have been considered conventional apparatuses at the time the invention was made, variations on the diameter of the of the cap or the gauge of the needle would have been considered obvious choices in the process of designing the infusion system.

In relation to **claim 7**, since the evidence above demonstrates that spring elements would have been considered conventional in the art at the time the invention was made, any variations in manufacturing materials or wall thickness would have been considered an obvious design choice. In relation to **claim 8**, as stated above, whether the spring elements and the cams are designed to be integral or separable would have been considered an obvious design choice. **Claim 9** is considered a product by process claim and the claimed "one part" has been demonstrated to be conventional in the art by the evidence presented in this rejection. In relation to **claim 10**, Aoki demonstrates the conventionality of using plastics in a fixing device. In relation to **claim 11**, the Lynn patent discloses the use of PCTG to manufacture the fixing device. Accordingly, for a person of ordinary skill in the art, modifying the manufacturing materials of the apparatus disclosed by Ashkenaz with PCTG would have been considered another obvious design choice.

In relation to **claim 22**, the cited patents in this rejection disclose spring elements that are segments of a surface area of the device. In relation to **claim 23**, the evidence presented in this rejection suggests that the cam tips are designed to make contact with the instrument being inserted into the fixing device; therefore, variations in the shapes or dimensions of the inserted instruments would have required changes to the dimensions or shapes of the tips in order to properly secure inserted instruments. Therefore, such variations would have been considered obvious design choices. In relation to **claims 24 and 25**, since the evidence presented in this rejection demonstrates the conventionality of fixing devices and spring elements, changes in their elasticity or dimensions would have also been considered obvious design choices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel A. Mendez whose telephone number is 571-272-4962. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Manuel A. Mendez/

Primary Examiner, Art Unit 3763

Manuel A. Mendez
Primary Examiner
Art Unit 3763

MM